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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,142	02/07/2002	Michael Helmlinger	480744.90518	1431

26710 7590 08/27/2003

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EXAMINER

CARTAGENA, MELVIN A

ART UNIT	PAPER NUMBER
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3754

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,142	HELMLINGER, MICHAEL	
	Examiner	Art Unit	
	Melvin A. Cartagena	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: The reference number 29 is missing in the drawings. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 7 and 10 are objected to because of the following informalities: claim 7, recites the limitation "on the latter" in line 2. There is insufficient antecedent basis for this limitation in the claim. it appears the word "latter" refers to the housing.

In claim 10, the reference number 35 is used to indicate a guide sleeve, in the specification the guide sleeve is indicated by reference number 25. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and/or use the invention. Examiner asks how does the ring section detach from the housing?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8, 13, 16, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,131,217 to Sandegren.

Sandegren shows a dispenser for multiple discharges of media, an actuator means 3, a dispensing discharge opening 17, an elastically deformable bridge 1, a ring section 4 and a housing 21.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 10, 14, 15, 17-19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,131,217 to Sandegren in view of US 6,446,839 to Ritsche.

Sandegren shows all claimed features as discussed above except for a piston pump, a coaxial guide sleeve and locking means. Ritsche shows a piston pump 21, lacking tabs 18 and a coaxial guide sleeve 13. It would have been obvious to a person with ordinary skill in the art at

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the time the invention was made to modify the device of Sandegren to include a piston pump with axial sleeve and a locking mechanism as taught by Ritsche to provide a housing for conventional glass ampoules, prevent undesired movement and obtain accurate and consistent medication delivery.

9. Claims 11, 12 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,131,217 to Sandegren in view of US 3,512,524 to J. Drewe.

Sandegren shows all claimed features as discussed above except for the material bridge constructed as a bellow and the actuator element surrounding the bridge. Drewe shows a medication device with a bridge constructed as a bellow as seen in Fig. 1 and the actuator 9 surrounding the bellow. It would have been obvious to a person with ordinary skill in the art at the time the invention was made to modify the bridge of Sandegren with a bellow as taught by Drewe since the above combination represents a substitute of well known alternative equivalent resilient means which is well known within the level of skill in the art.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Salisbury shows a disposable syringe. Boucher shows a bladder wash method.

Amneus shows a portable measured volume dispenser. Hansen shows a container for delivery of flow-able material. Shcherbina shows an injection device with bellowed reservoir.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin A. Cartagena whose telephone number is (703) 308-5810. The examiner can normally be reached on M-F (7:30AM to 4:00 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Louis G. Mancene can be reached on (703) 308-2696. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

MAC 8/22/03
MAC



Gene Mancene
Supervisory Patent Examiner
Group 3700